Cardiovascular Medicine and Cardiac Arrhythmias
An Incorporated Medical Group

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Division of Dockets Management (HFA-305
5630 Fishers Lane, Room 1061
Rockville, MN 20852

Dear Sir/Madame:

I am writing in reference to the "Draft Guidance for Industry and FDA Staff" regarding "Functional Indications for Implantable Cardioverter Defibrillators" you sent out for review and comment on October 6, 2005. I applaud the effort involved in creating the 'functional guidelines,' and would like to offer my comments. In my clinical judgment defibrillation is the definitive therapy in ICD's, attributing to the mortality benefit thousands of patients have received. In fact, the majority of patients are programmed with defibrillation as the only therapy turned on in the device, even when the option of antitachycardia pacing is present. There appears to be an inconsistency in the draft guidelines document. The references on pages 2 and 4 refer to the intended treatment to be antitachycardia pacing and/or high energy shocks (defibrillation), and on page 3 referencing antitachycardia pacing and high energy shocks. Based on clinical practice, it seems the functional guideline to operate at a level that provides a broad guideline for devices in this category, it seems the consistent use of "and/or" is the most clinically appropriate in all cases when the reference to therapy is defined.

I appreciate your consideration of my comments.

Sincerely,

R Hardwin Mead

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